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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

Penny Rickhoff, Plaintiff, v. United States Secretary for the Department of Health and Human Services, Defendant.	No. CV-11-2189-PHX-DGC **ORDER**

Plaintiff Penny Rickhoff has commenced this action under 42 U.S.C. § 1395w-104(h)(1) for review of a final decision of the Secretary of Health and Human Services ("Defendant") that denied Plaintiff's claim for coverage of a particular prescription drug. Doc. 1. The dispute centers on whether the drug at issue is covered by Medicare Part D. Plaintiff filed her opening brief on August 8, 2012 (Doc. 18), and Defendant filed a response on September 13, 2012 (Doc. 19). No reply brief was filed. For reasons that follow, the Court will affirm Defendant's decision.[1]

I. Background.

A. Statutory and Regulatory Overview.

Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq.*, provides for the Medicare program, a federally funded and administered health insurance program for qualifying individuals. Defendant administers the Medicare program through the Centers

[1] Plaintiff's request for oral argument is denied because the Court finds that the issues have been fully briefed and that oral argument will not aid the Court's decision. *See* Fed. R. Civ. P. 78(b); *Partridge v. Reich*, 141 F.3d 920, 926 (9th Cir. 1998).

for Medicare and Medicaid Services ("CMS"), a federal agency within the Department of Health and Human Services. Since 2006, Medicare has included Medicare Part D, a voluntary prescription drug benefits program for Medicare enrollees. 42 U.S.C. § 1395w-101 *et seq.* The CMS provides drug coverage to Part D enrollees through private Part D Plans ("PDP") offered and administered by private PDP sponsors. *Id.* PDP sponsors are required to provide qualified prescription drug coverage. 42 U.S.C. §§ 1395w-102-1395w-104.

To qualify as a covered Part D drug, a drug must be used for a "medically accepted indication." 42 U.S.C. § 1395w-102(e)(1); *see also* 42 C.F.R. § 423.100 (defining "Part D drug"); *Kilmer v. Leavitt*, 609 F. Supp. 2d 750, 753-54 (S.D. Ohio 2009) (holding that the plain language of the definition limits the definition to drugs used for a "medically accepted indication"); *U.S. ex. rel. Fox Rx., Inc. v. Omnicare Inc.*, No. 1:11-cv-00962-WSD, 2012 U.S. Dist. LEXIS 145036, at *23-25 (N.D. Ga. 2012) (same); *but see Layzer v. Leavitt*, 770 F. Supp. 2d 579, 584-85 (S.D.N.Y. 2011) (holding that the term 'includes' "shall not be deemed to exclude other things otherwise within the meaning of the term defined."). A "medically accepted indication" means "any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 301 *et seq.*], or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in section (g)(1)(B)(i) of this section." 42 U.S.C. § 1396r-8(k)(6). The compendia are (1) the American Hospital Formulary Service Drug; (2) the United States Pharmacopeia-Drug Information; and (3) the DRUGDEX Information Systems (herein collectively referred to as "Compendia"). 42 U.S.C. § 1396r-8(g)(1)(B)(i).

Effective January 1, 2009, Congress expanded the definition of "medically accepted indication" to include off-label usage of Food and Drug Administration ("FDA") approved drugs when used in an anticancer chemotherapeutic regimen as supported by peer-reviewed medical literature. *See* 42 U.S.C. § 1395w-102(e)(4)(A)(i). Congress did not, however, change the Compendia requirement for non-cancer related,

off-label drug therapies.

In accordance with the Medicare Act, Defendant has created an administrative review process that allows enrollees to appeal a PDP's coverage determination. 42 U.S.C. § 1395w-104(g), (h) (incorporating requirements of § 1395w-22(g)); 42 C.F.R. § 423.560 *et seq.* A coverage determination includes a decision not to provide or pay for a Part D drug, the failure to provide a timely coverage determination when delay would adversely affect the enrollee's health, or a decision concerning an exceptions request. 42 C.F.R. § 423.566(b).

B. Factual and Procedural History.

Plaintiff is a Medicare beneficiary who suffers from chronic non-cancer pain stemming from "failed back syndrome" and other diagnoses and injuries. A.R. 338-39, 567-68. On September 21, 2010, Plaintiff's physician, Dr. Anita Mayer, submitted a request for prior authorization to MedicareRX Rewards Plus, Plaintiff's PDP ("the Plan"), for a prescription of transmucosal fentanyl lozenge (Actiq 800 mcg). A.R. 64, 323. The Plan denied the prior authorization request on September 23, 2010 (A.R. 343), and reaffirmed that denial on October 19, 2010 (A.R. 415-16).

Plaintiff pursued an administrative appeal, which eventually led to a May 5, 2011, decision of an administrative law judge ("ALJ") affirming the Plan's denial of coverage. A.R. 40-58. The ALJ found that the FDA had approved fentanyl lozenges such as Actiq "only for breakthrough pain for cancer patients who have become habituated to other pain killing drugs." A.R. 56. The ALJ further found that Plaintiff had not been prescribed Actiq for cancer breakthrough pain but rather for other diagnoses "which have not been deemed 'medically accepted indications' by the FDA." A.R. 56. The ALJ determined that the Compendia "are not inconsistent with the FDA's position that cancer breakthrough pain is the only medically accepted indication for the fentanyl lozenge." A.R. 56. The ALJ also found that the record failed to support the medical necessity of fentanyl in lozenge form, as opposed to fentanyl in skin patch or injection form. A.R. 57.

Plaintiff's appeal of that decision to the Medicare Appeals Council ("MAC")

resulted in a September 8, 2011, decision that adopted the findings and conclusions of the ALJ. A.R. 8. The MAC agreed with the ALJ that Plaintiff presented a "sympathetic and compelling case," but concluded nonetheless that "the adjudicator is bound to follow Medicare law and regulations, which do not provide an exception when the drug, as used, does not meet the legal definition of a Part D drug." A.R. 8.

II. Standard of Review.

Under 42 U.S.C. § 1395w-104(h)(1), which incorporates the requirements of 42 U.S.C. § 1395w-22(g)(5), judicial review of Defendant's decision in this case is governed by 42 U.S.C. § 405(g).[2] *See* 42 U.S.C. § 1395w-22(g)(5); *see also Kilmer*, 609 F. Supp. 2d at 752-53 (applying Social Security standard of review to claim for Part D drug benefits). Section 405(g) also governs judicial review of claims for benefits under the Social Security Act. Thus, Defendant's denial of a Part D coverage claim will be vacated "only if it is not supported by substantial evidence or is based on legal error." *Robbins v. Soc. Sec. Admin.*, 466 F.3d 880, 882 (9th Cir. 2006); *Flaten v. Sec. of Health & Human Servs.*, 44 F.3d 1453, 1457 (9th Cir. 1995) (noting that the Court's scope of review pursuant to 42 U.S.C. § 405(g) "is limited"). "'Substantial evidence' means more than a mere scintilla, but less than a preponderance, i.e., such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Id.* In determining whether the decision is supported by substantial evidence, the Court must consider the record as a whole, weighing both the evidence that supports the decision and the evidence that detracts from it. *Reddick v. Charter*, 157 F.3d 715, 720 (9th Cir. 1998).

III. Discussion.

Plaintiff argues that Defendant's decision results in unfair discrimination because it limits coverage of fentanyl lozenges to cancer-patients when the injection and skin

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[2] Section 405(g) provides that "[t]he findings of the Commissioner of Social Security as to any fact, if supported by substantial evidence, shall be conclusive, and where a claim has been denied . . . because of failure of the claimant or such individual to submit proof in conformity with any regulation prescribed under subsection (a) of this section, the court shall review only the question of conformity with such regulations and the validity of such regulations." 42 U.S.C. § 405(g).

patch form of fentanyl is covered regardless of diagnosis. Plaintiff also contends that fentanyl in lozenge form is medically necessary to treat Plaintiff's breakthrough pain. Doc. 18 at 13. Plaintiff does not argue that fentanyl in lozenge form was prescribed to her for a "medically accepted indication" or that it otherwise is a covered Part D drug. Doc. 18 at 9.

A. Discrimination Challenge.

In adopting the ALJ's decision, the MAC noted that Plaintiff had argued that the decision to deny her coverage resulted in discrimination based on diagnosis type because she would not have been denied coverage if she had been diagnosed with cancer. A.R. 6. The MAC pointed to the ALJ's response "that the law covering Medicare Part D prescription drug benefit requires that drugs eligible for coverage must be used for a medically accepted indication," and that since "fentanyl lozenge is only approved by the FDA for breakthrough cancer pain, payment cannot be made." A.R. 6.

Plaintiff makes the same argument here, contending that Defendant's decision is discriminatory because fentanyl in lozenge form is a covered Part D drug for cancer patients suffering from breakthrough pain, but is not covered for non-cancer patients suffering from similar breakthrough pain. Doc. 18 at 9. Plaintiff argues that a "distinction based on labeling creates an unjust result." *Id.*

Plaintiff appears to be making an equal protection challenge, but she does not assert that this case involves a suspect class or fundamental right. As a result, any equal protection challenge is governed by the rational basis test. *See F.C.C. v. Beach Comms., Inc.*, 508 U.S. 307, 313 (1993) ("In areas of social and economic policy, a statutory classification that neither proceeds along suspect lines nor infringes fundamental constitutional rights must be upheld against equal protection challenge if there is any reasonably conceivable state of facts that could provide a rational basis for the classification."). The Court agrees with the conclusion in *Kilmer* that the statutory scheme as applied to fentanyl in lozenge form survives rational-basis review:

> The statutory scheme at issue here survives rational-basis review. It is axiomatic that in establishing the Medicare scheme, Congress was faced with difficult decisions about what to cover and what not to cover. These decisions mandate making distinctions, or else the resulting prescription drug benefit program would cover everything for everyone, all the time. *See Minnesota Senior Fed'n, Metro. Region v. United States*, 273 F.3d 805, 808 (8th Cir.2001) ("Distributing Social Security and Medicare benefits is a massive undertaking which 'requires Congress to make many distinctions among classes of beneficiaries while making allocations from a finite fund.' *Bowens v. Owens*, 476 U.S. 340, 345 (1986). Accordingly, the Supreme Court has rejected numerous equal protection challenges to the ways in which these benefits are distributed."). And for purposes of today's constitutional inquiry, it does not matter "whether the conceived reason for the challenged distinction actually motivated the legislature" or whether there is even an explanation of the distinction on the record supported by evidence and empirical data. *Beach Communications, Inc.*, 508 U.S. at 315. What matters is that this rationale can support the distinction that Kilmer attacks.
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> The foregoing rationale alone proves dispositive of Kilmer's argument. *See id.* at 315–16 ("Defining the class of persons subject to a regulatory requirement – much like classifying governmental beneficiaries – 'inevitably requires that some persons who have an almost equally strong claim to favored treatment be placed on different sides of the line, and the fact [that] the line might have been drawn differently at some points is a matter for legislative, rather than judicial, consideration.'" (quoting *United States Railroad Retirement Bd. v. Fritz*, 449 U.S. 166, 179 (1980))).

See 609 F. Supp. 2d at 758.

B. Medical Necessity Exception.

The ALJ noted that Plaintiff may have been entitled to a "dose or form" exception through the formulary exception process. A.R. 57. The ALJ found, however, that there was insufficient evidence to support the medical necessity of the prescription in lozenge form as opposed to skin patch or injection form. *Id.* In adopting the ALJ's decision, the MAC noted that "[t]he ALJ considered an exception based on the dosage of the drug fentanyl, but concluded that there is insufficient evidence in this particular medical record." A.R. 7 (quotations and citations omitted).

Plaintiff reasserts her claim that she is entitled to an exception for medical

necessity under the process outlined in 42 C.F.R. § 423.578. Doc. 18 at 10. The regulation provides that "[t]he Part D plan sponsor must grant an exception whenever it determines that the non-preferred drug for treatment of the enrollee's condition is medically necessary, consistent with the physician's or other prescriber's statement under paragraph (a)(4) of this section, and that the drug would be covered but for the fact that it is an off-formulary drug." 42 C.F.R. § 423.578(b). Plaintiff argues that statements from her treating physician and prescribing doctor provide sufficient evidence to establish medical necessity. Doc. 18 at 11.

As Defendant notes, the exception process was developed to allow enrollees to seek coverage for a non-preferred or a non-formulary Part D drug, but not to permit enrollees to obtain coverage for drugs that do not otherwise qualify as Part D drugs. As explained in 42 C.F.R. § 423.578(e), "[n]othing in this section may be construed to allow an enrollee to use the exceptions processes set out in this section to request or be granted coverage for a prescription drug that does not meet the definition of a Part D drug."

Plaintiff has not shown that fentanyl in lozenge form otherwise meets the definition of a Part D drug for her condition. The fact that the injection and skin patch forms of fentanyl are covered under the formulary used by Plaintiff's Plan (A.R. 6) does not mean that fentanyl in any form or dosage is a covered Plan D drug. Fentanyl in lozenge form is not a "medically accepted indication" for non-cancer patients and thus is not a covered Part D drug. 42 U.S.C. § 1395w-102(e)(1). As a result, Plaintiff is not entitled to an exception under 42 C.F.R. § 423.578.

IT IS ORDERED:

1. Defendant's decision is **affirmed**.

2. The clerk is directed to **terminate** this action.

Dated this 11th day of December, 2012.

David G. Campbell
United States District Judge